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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

FELISHA DITONNO *et al.*, Plaintiffs, vs. BAYER CORP.; BAYER HEALTHCARE LLC; BAYER ESSURE INC., (F/K/A CONCEPTUS, INC.); BAYER HEALTHCARE PHARMACEUTICALS, INC.; and DOES 1-100, inclusive, Defendants.	Case No. 3:17-CV-3640-HSG **NOTICE OF MOTION AND MOTION TO DISMISS PLAINTIFFS' COMPLAINT; MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT** [Filed concurrently with Request for Judicial Notice and [Proposed] Order] Judge: TBD (Pending Judicial Assignment-administrative motion to relate cases pending) Date: TBD (Pending Judicial Assignment) Time: TBD (Pending Judicial Assignment) Place: TBD (Pending Judicial Assignment)

NOTICE OF MOTION AND MOTION TO DISMISS

TO ALL PARTIES AND THEIR ATTORNEYS OF RECORD:

PLEASE TAKE NOTICE that at a date, time, and location to be determined upon final judicial assignment, in the appropriate Courtroom of the above-entitled Court, Defendants Bayer HealthCare LLC and Bayer Essure Inc. and Specially Appearing Defendants Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") will and hereby do move to dismiss Plaintiffs' Complaint [D.E. 1-1], under Federal Rules of Civil Procedure 8, 9(b), and 12(b)(1), (6).

The motion is based on the following grounds:

1. Essure® is a Class III medical device with premarket approval from the U.S. Food & Drug Administration. Plaintiffs' causes of action would impose legal requirements "different from, or in addition to," the requirements imposed by FDA. 21 U.S.C. § 360k(a)(1). As a result, Plaintiffs' claims challenging the Essure device's design, manufacturing, training, labeling, warnings, and warranties are expressly preempted because they fail to identify a violation of FDA "requirements related to" their devices as well as "a causal nexus between the alleged injur[ies] and the violation" of federal requirements. *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013); *see Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Norman v. Bayer Corp.*, 2016 WL 4007547, at *3-6 (D. Conn. July 26, 2016) (holding claims expressly preempted), *appeal filed*; *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085, 1094-99 (N.D. Cal. 2016) (same); *Richardson v. Bayer HealthCare Pharms. Inc.*, 2016 WL 4546369, at *4-9 (D. Idaho Aug. 30, 2016) (same); *Burrell v. Bayer Corp.*, 2017 WL 1955333, at *5-9 (W.D.N.C. May 10, 2017) (same), *appeal filed*.

2. Plaintiffs' causes of action are also impliedly preempted because they seek to second-guess FDA. The agency has the exclusive authority to regulate Class III medical devices like Essure, and has decided—numerous times—that Essure is safe and effective. Plaintiffs' attempts to enforce FDA requirements directly infringe upon that exclusive authority; they accordingly are impliedly preempted. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *Perez v. Nidek Co. Ltd.*, 711 F.3d 1109, 1120 (9th Cir. 2013); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204-08 (8th Cir. 2010); *see also* 21 U.S.C. § 337(a); *Norman*,

2016 WL 4007547, at *3-6 (holding claims impliedly preempted), *appeal filed*; *De La Paz*, 159 F. Supp. 3d at 1094-99 (same); *Richardson*, 2016 WL 4546369, at *4-9 (same); *Burrell*, 2017 WL 1955333, at *5-9 (same), *appeal filed*.

3. Plaintiffs' causes of action should also be dismissed because they have not adequately pled facts stating a valid claim. *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007); Fed. R. Civ. P. 12(b)(6); *see McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 817-18, 824, 836 (E.D. Pa. 2016); *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *6.

4. Plaintiffs' fraud claims should be dismissed because they have not pleaded their cause of action with sufficient particularity. *See* Fed. R. Civ. P. 9(b); *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009).

5. Plaintiffs' implied warranty claim is barred under California law because Plaintiffs are not in privity with Bayer, as required to state a claim for breach of implied warranty.

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6. The non-California Plaintiffs' claims against Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. should be dismissed for lack of personal jurisdiction. *See* Fed. R. Civ. P. 12(b)(1); *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, No. 16-466, 137 S. Ct. 1773 (2017); *Daimler AG v. Bauman*, 134 S. Ct. 746, 760-61 & n.19 (2014).

Dated: June 30, 2017

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By: */s/ Alycia A. Degen*

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INTRODUCTION

The Complaint is meritless. Numerous other courts—including this Court—have rejected virtually identical claims, which are preempted by federal law, and do not meet federal pleading standards. *See*, *e.g.*, *De La Paz v. Bayer Healthcare LLC*, 159 F. Supp. 3d 1085 (N.D. Cal. 2016) (all claims dismissed with leave to amend some claims; plaintiff then voluntarily dismissed) (Alsup, J.); *Norman v. Bayer Corp.*, 2016 WL 4007547 (D. Conn. July 26, 2016) (all claims dismissed with prejudice), *appeal filed*; *Burrell v. Bayer Corp.*, 2017 WL 1955333 (W.D.N.C. May 10, 2017) (all claims dismissed with prejudice), *appeal filed*; *Richardson v. Bayer HealthCare Pharms. Inc.*, 2016 WL 4546369 (D. Idaho Aug. 30, 2016) (almost all claims dismissed; plaintiff then voluntarily dismissed case with prejudice); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 838-39 (E.D. Pa. 2016) (dismissing almost all claims); *McLaughlin v. Bayer Corp.*, Nos. 14-7315 *et al*., 2017 WL 697047, at *19 (E.D. Pa. Feb. 21, 2017) (further narrowing claims in amended complaint).[1]

These courts have had no trouble dismissing the claims at issue because, at bottom, plaintiffs are attempting to second-guess the United States Food & Drug Administration ("FDA"). *See Riegel v. Medtronic, Inc.*, 552 U.S. 312, 321-22 (2008); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001); *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204-08 (8th Cir. 2010); *see also* 21 U.S.C. §§ 360k(a), 337(a). FDA has the exclusive authority to regulate Class III medical devices like Essure, and has decided—numerous times—that Essure is safe and effective. FDA has balanced the benefits and risks of the device and confirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." FDA, News Release (Feb. 29, 2016) (RJN, Ex. F). Consistent with this wealth of precedent, this Court should dismiss the Complaint. The Court also should dismiss the Complaint because Plaintiffs failed to state valid causes of action, and the Court lacks personal jurisdiction over

[1] Numerous state courts have done the same. *See Medali v. Bayer HealthCare LLC*, No. RG15771555 (Cal. Super Ct. Feb. 16, 2016) (demurrer sustained with leave to amend certain claims) (order attached as Exhibit A to concurrently filed Request for Judicial Notice ("RJN")); *Noris v. Bayer Essure, Inc.*, No. BC589882, (Cal. Super. Ct. Apr. 26, 2016) (same) (transcript excerpts attached as RJN, Ex. B); *Williams v. Bayer Corp.*, No. 15BA-CV02526 (Mo. Cir. Ct. July 18, 2016) (complaint dismissed with prejudice) (RJN, Ex. C); *Lance v. Bayer Essure Inc.*, RG16809860 (Cal. Super. Ct. Aug. 2, 2016) (RJN, Ex. D); *Journey v. Bayer Corp.*, JCCP No. 4887 (Cal. Super. Ct. Apr. 12, 2017) (demurrer sustained in part) (RJN, Ex. E).

the out-of-state Plaintiffs' claims against Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc.

BACKGROUND

A. Statutory and Regulatory Background.

Congress has spoken. The Medical Device Amendments ("MDA") to the Federal Food, Drug, and Cosmetic Act ("FDCA") grant FDA exclusive authority to regulate medical devices through a comprehensive statutory "regime of detailed federal oversight." *Riegel*, 552 U.S. at 316. To eliminate differing state regulation, Congress adopted a "general prohibition on non-Federal regulation" of medical devices by incorporating an express-preemption clause into the MDA. H.R. Rep. No. 94–853, at 45 (1976). Thus, no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable . . . to the device" under federal law. 21 U.S.C. § 360k(a).

Instead of state regulation, FDA provides the necessary oversight. Under this regime, "each medical device is classified according to the stringency of regulatory control necessary to ensure safety and effectiveness." *Yale-New Haven Hosp. v. Leavitt*, 470 F.3d 71, 74 (2d Cir. 2006). A device intended "for a use in supporting or sustaining human life," or that otherwise "presents a potential unreasonable risk of illness or injury" is deemed a Class III device. 21 U.S.C. §§ 360c(a)(1)(C)(i)-(ii). FDA subjects a small percentage of innovative Class III devices, such as Essure, to the most "rigorous" level of FDA scrutiny. These devices must receive Premarket Approval ("PMA") before they can be marketed or sold. *Riegel*, 552 U.S. at 318; *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001).

To receive such approval, the device manufacturer "must submit what is typically a multivolume application," and the "FDA spends an average of 1,200 hours reviewing each application," ultimately "grant[ing] premarket approval only if it finds there is a 'reasonable assurance' of the device's 'safety and effectiveness.'" *Riegel*, 552 U.S. at 317-18 (quoting 21 U.S.C. § 360e(d)); *see also Walker v. Medtronic, Inc.*, 670 F.3d 569, 572-73 (4th Cir. 2012) (describing premarket approval process). A "manufacturer must furnish" to FDA "detailed information about

the device's testing, design, components, performance standards, manufacturing, packaging, and labeling." *Yale-New Haven*, 470 F.3d at 74. FDA then "'weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.'" *Riegel*, 552 U.S. at 318 (quoting 21 U.S.C. § 360c(a)(2)(C)).

As part of this process, FDA reviews a device's proposed labeling, which includes the Instructions for Use ("IFU") (for physicians) and Patient Information Booklet ("PIB") (for patients). The agency "evaluates safety and effectiveness under the conditions of use set forth on the label," and "must determine that the proposed labeling is neither false nor misleading" before granting approval. *Id.* (citing 21 U.S.C. §§ 360c(a)(2)(B), 360e(d)(1)(A)). Once a device has been approved, a manufacturer cannot make changes to the labeling without FDA permission, 21 U.S.C. § 360e(d)(6)(A)(i), under "largely the same criteria" as the initial application. *Riegel*, 522 U.S. at 319 (citing 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(c)). The statute likewise "forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* (citing 21 U.S.C. § 360e(d)(6)(A)(i)). FDA may demand additional information from the manufacturer at any time, *see* 21 U.S.C. § 360e(c)(1)(H), and may require revisions to any component of the application, *see* 21 C.F.R. § 814.44(c). Only upon successfully "running the gauntlet of the PMA process," *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 494 (1996), may a Class III device lawfully be marketed in the United States.

Furthermore, a device manufacturer's obligations under federal law do not end with pre-market approval. *See Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1336 (10th Cir. 2015). By design, FDA enjoys wide and exclusive enforcement authority. Congress has made clear that actions to enforce the FDCA "shall be by and in the name of the United States," 21 U.S.C. § 337(a), and this judgment forecloses any private right of action under that statute, *see Buckman*, 531 U.S. at 349 n.4. FDA may investigate manufacturers, and the agency "has at its disposal a variety of enforcement options that allow it to make a measured response" to any violations it uncovers. *Buckman*, 531 U.S. at 349; *see also* 21 U.S.C. §§ 332, 333, 334.

B. Factual Background.

FDA has long recognized that Essure is a safe and effective method of permanent female contraception. Essure consists of two "micro-inserts" that are placed in a patient's fallopian tubes by her doctor. In 2002, FDA granted Essure PMA as a Class III device, and FDA has never withdrawn or suspended that PMA. *See* FDA, Premarket Approval Order for the Essure System (RJN, Ex. G at 4); Summary of Safety and Effectiveness Data for Essure System (RJN, Ex. H); FDA, Essure System PMA Supplements (RJN, Ex. I); FDA, Essure Regulatory History (RJN, Ex. J). Rather, FDA has approved numerous supplements, including as recently as December 2016. FDA, PMA Supplements (RJN, Ex. I). FDA repeatedly has reviewed and approved Essure's design, construction, manufacturing, testing, warnings, instructions for use, patient information, and all other labeling. FDA, Premarket Approval Order (RJN, Ex. G at 4); Safety Summary (RJN, Ex. H); Professional Labeling (2002) ("2002 IFU") (RJN, Ex. K); Professional Labeling (2013) ("2013 IFU") (RJN, Ex. L); ESS305 Post-Approval Study: 12 month interim report (RJN, Ex. M). In fact, FDA has rejected challenges to the device, reconfirming that "FDA believes Essure remains an appropriate option for the majority of women seeking a permanent form of birth control." FDA News Release (RJN, Ex. F); *see also* FDA, *FDA Activities:* (RJN, Ex. N.) ("The FDA continues to believe that the benefits of the device outweigh its risks . . . .").

Plaintiffs are seven unrelated women, who are from five different states—only two of whom claim to be citizens of California. They allege that Essure was placed in their fallopian tubes over eight years, between 2007 and 2015, and that they experienced various injuries, including "severe abnormal menstrual pain, abnormal menstrual cycle, excessive bleeding, severe pelvic pain, back pain, abdominal pain, pain during intercourse, headaches, allergic reaction, mood swings, migration of the device, unwanted pregnancy, and fatigue." Compl. ¶¶ 121, 131, 141, 151, 161, 171, 181. Many then reported these symptoms to their physicians, and some Plaintiffs eventually had the devices removed.

Plaintiffs assert five causes of action against Bayer: (1) negligence, (2) strict products liability, (3) breach of express warranty, (4) breach of implied warranty, and (5) fraud.

STANDARD OF REVIEW

A Rule 12(b)(6) motion to dismiss should be granted if a plaintiff is unable to articulate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). "[A] plaintiff's obligation to provide the 'grounds' of his 'entitle[ment] to relief' requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Id*. at 545. "Nor does a complaint suffice if it tenders 'naked assertion[s]' devoid of 'further factual enhancement.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*). The Court is "not required to accept as true conclusory allegations which are contradicted by documents referred to in the complaint," *Sprewell v. Golden State Warriors*, 266 F.3d 979, 990 (9th Cir. 2001) (citations omitted), or any "unwarranted inferences." *Fields v. Legacy Health Sys.*, 413 F.3d 943, 950 n.5 (9th Cir. 2005). Additionally, claims sounding in fraud must be pled with particularity pursuant to Rule 9(b). *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1125 (9th Cir. 2009).

ARGUMENT

Plaintiffs' claims are preempted because they "seek[] to impose new standards for safety and effectiveness that go beyond . . . federal requirements," have "not alleged specific federal law violations supporting a parallel claim," and raise claims "entirely based on alleged federal violations." *Martin v. Medtronic, Inc.*, 2017 WL 825410, at *5 (E.D. Cal. Feb. 24, 2017) (holding that federal law preempts manufacturing, failure to warn, warranty, and fraud claims). As in that case, they are meritless. *Id.* at *16. Numerous well-reasoned decisions by this Court and others have addressed nearly identical claims concerning Essure, and they have concluded that they are preempted by federal law and fail to satisfy federal pleading standards. *See De La Paz*, 159 F. Supp. 3d 1085. This Court should dismiss this case for the same reasons. Moreover, the Court lacks personal jurisdiction over non-California Plaintiffs' claims against Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. and should sever and dismiss those claims under Federal Rules of Civil Procedure 12(b)(1) and 21.

I. PLAINTIFFS' CLAIMS ARE PREEMPTED BY FEDERAL LAW.

As this Court and others have held in dismissing similar complaints against Essure, federal law preempts claims like Plaintiffs' here. *See De La Paz*, 159 F. Supp. 3d 1085; *Norman*, 2016 WL 4007547; *Richardson*, 2016 WL 4546369; *Burrell*, 2017 WL 1955333; *see also McLaughlin*, 172 F. Supp. 3d at 839-40; *McLaughlin*, 2017 WL 697047, at *19. Federal law expressly preempts any state tort claim against medical devices that would impose requirements "different from, or in addition to, any requirement" imposed by FDA. 21 U.S.C. § 360k(a)(1); *Riegel*, 552 U.S. at 321; *De La Paz*, 159 F. Supp. 3d at 1091; *Burrell*, 2017 WL 1955333, at *4; *Richardson*, 2016 WL 4546369, at *3-4; *Norman*, 2016 WL 4007547, at *2.[2] Claims regarding Essure are expressly preempted unless plaintiffs adequately allege (and ultimately prove) a violation of FDA "requirements related to" her device as well as "a causal nexus between the alleged injury and the violation" of federal requirements. *Houston v. Medtronic, Inc.*, 957 F. Supp. 2d 1166, 1174 (C.D. Cal. 2013); *see also Medali*, No. RG15771555, at 2 (RJN, Ex. A); *Noris*, No. BC589882, Tr. at 25:20-25 (RJN, Ex. B); *Williams*, No. 15BA-CV0252, at 1 (RJN, Ex. C).

In addition, because FDA has extensive and exclusive authority to enforce its own requirements, federal law impliedly preempts claims based solely on the violation of FDA requirements. *Buckman*, 531 U.S. at 349 n.4; *see* 21 U.S.C. § 337(a) (all actions to enforce the FDCA "shall be by and in the name of the United States"). Plaintiffs cannot second-guess FDA or its decision on how to enforce those requirements. *Riegel*, 552 U.S. at 343. As a result, a "claim may be impliedly preempted when the state-law claim is in substance (even if not in form) a claim for violating the FDCA—that is, when the state claim would not exist if the FDCA did not exist." *McConologue v. Smith & Nephew, Inc.*, 8 F. Supp. 3d 93, 101 (D. Conn. 2014).

Thus, state-law claims concerning medical devices with pre-market approval—such as

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[2] These decisions analyze the issues under the rubric of both preemption and federal pleading standards. *See, e.g.*, *Norman*, 2016 WL 4007547, at *5; *McLaughlin*, 172 F. Supp. 3d at 834-45. Under both analyses, the result is the same: the claims fail as a matter of law and must be dismissed. Further, the two issues are interrelated. A failure to plead adequately that a federal violation caused the particular plaintiff's injuries, for instance, results in both a failure to state a claim under federal pleading standards and implied preemption. *Horowitz v. Stryker Corp.*, 613 F. Supp. 2d 271, 282 (E.D.N.Y. 2009). While this brief focuses on the complaint's deficiencies as a matter of preemption, the claims are also inadequately pled for many of the same reasons. *See*, *e.g.*, § II, *infra*.

Essure—are preempted unless they fit within a "narrow gap": "The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*)." *Perez v. Nidek Co.*, 711 F.3d 1109, 1120 (9th Cir. 2013). To fit within this narrow gap, a plaintiff must plead and ultimately prove (1) that Bayer violated some federal requirement; (2) that this federal violation also ran afoul of an independent and "parallel" state law requirement; and (3) that the federal violation caused her individual injuries. *Id.* at 1120; *Martin*, 2017 WL 825410, at *5; *Norman*, 2016 WL 4007547, at *2.

Plaintiffs' claims do not fall within this "narrow gap," and are therefore preempted. In their five causes of action against Bayer, they raise six meritless theories of liability: (1) Essure is defectively designed; (2) Bayer deviated from FDA-approved standards in manufacturing Plaintiffs' devices; (3) Bayer failed to train Plaintiffs' physicians adequately; (4) Bayer failed to warn Plaintiffs and their physicians of Essure's risks; (5) Bayer failed to report adverse events to FDA; and (6) Bayer misrepresented Essure's safety and efficacy. Their claims are preempted.

A. Federal Law Preempts Plaintiffs' Design Defect Claims.

Plaintiffs' causes of action for negligence and breach of implied warranty include claims that Essure was defectively designed or that its design was unreasonably dangerous. *See, e.g.*, Compl. ¶ 268 ("Essure was not reasonably safe for its expected purpose, nor reasonably fit for the ordinary purpose for which it was sold[.]").

This claim is preempted, because FDA specifically approved the design of Essure and found that the design is safe and effective for use as a permanent contraceptive. *See* p.3-4, *supra*. FDA has reaffirmed this judgment repeatedly, including after reviewing the same challenges Plaintiffs raise here. *See* FDA News Release (RJN, Ex. F); FDA Activities (RJN, Ex. N). As *De La Paz* explained, design defect claims "cannot survive preemption, inasmuch as [plaintiff] cannot allege that Bayer departed from the design for Essure approved by the FDA." *De La Paz*, 159 F. Supp. 3d at 1095. Likewise, the claim for breach of implied warranty is preempted because "[a] determination of whether the Essure device is fit for ordinary use bears directly on its safety and

effectiveness," as found by the FDA. *Id.* at 1097. In short, the Court should dismiss these claims because "[a] common law tort that presupposes a Class III device should have been designed in a manner other than that contemplated by its premarket approval is therefore expressly preempted by the MDA as interpreted by *Riegel*." *Walker*, 670 F.3d at 580 (emphasis added).

B. Federal Law Preempts Plaintiffs' Manufacturing Claims.

In their first cause of action, Plaintiffs bring claims based on the theory that there was a defect in the manufacturing process for Essure. Compl. ¶ 223. The Complaint alleges, in conclusory fashion, that Bayer "fail[ed] to properly meet the applicable standard of care by not complying with applicable federal regulations [in the manufacturing of Essure]," and that Bayer "carelessly and negligently [sold] and distribut[ed] Essure in violation of the CPMA and federal law." *Id.* And Plaintiffs assert that "[a]s a proximate and legal result" of Bayer's manufacturing conduct, they "suffered and will continue to suffer [injury]." *Id.* ¶ 225.

As numerous courts have held in evaluating nearly identical allegations, these claims are preempted. *See De La Paz*, 159 F. Supp. 3d at 1094-95; *Norman*, 2016 WL 4007547, at *3; *Richardson*, 2016 WL 4546369, at *5; *see also McLaughlin*, 2017 WL 697047, at *18 (E.D. Pa. Feb. 21, 2017); *Martin*, 2017 WL 825410, at *6. Plaintiffs' manufacturing claims are expressly preempted because they are not based on a failure to follow a "specific federal requirement in the PMA approval." *In re Medtronic*, 623 F.3d at 1206; *see also Martin*, 2017 WL 825410, at *6. "In order to avoid preemption on a manufacturing defect claim, [a] plaintiff must allege that her device was not manufactured in conformance with the specifications approved by the FDA." *Norman*, 2016 WL 4007457, at *3. Plaintiffs do not identify any specific federal manufacturing requirement for the Essure device.

Moreover, Plaintiffs offer "no description" of *how* Bayer violated any federal manufacturing requirements. *De La Paz*, 159 F. Supp. 3d at 1095. For instance, they offer no "plausible reason to think that [their] device[s] came from [a] non-conforming batch, or that [they] suffered from any other manufacturing defect," and no "facts that would make it plausible that the complications [they] suffered . . . were due to any defect in the device." *Norman*, 2016 WL 4007457, at *3. And

Plaintiffs "cannot state a claim based solely on Bayer's adulteration of certain Essure devices, since any such claim would 'exist solely by virtue of the [MDA],'" and therefore be preempted. *De La Paz*, 159 F. Supp. 3d at 1094-95 (quoting *Buckman*, 531 U.S. at 353). In other words, they are preempted because "whether the [devices] were modified so that they were 'adulterated' . . . rest[s] within the enforcement authority of the FDA, not this Court." *Perez*, 711 F.3d at 1120. Accordingly, as in *Norman*, *De La Paz*, *McLaughlin*, *Richardson*, and *Burrell*, Plaintiffs' claims fail and should be dismissed.

C. Federal Law Preempts Plaintiffs' Training Claims.

Plaintiffs also claim that Bayer "failed to adequately train the implanting physicians. Compl. ¶ 97(a), (b), This claim is preempted because Plaintiffs fail to "allege . . . any facts that give rise to a recognizable theory as to how any departure from the training guidelines may have caused [Plaintiffs' injuries]." *McLaughlin*, 172 F. Supp. 3d at 817. Indeed, Plaintiffs fail to allege how their doctors were trained, how that training violated FDA requirements, or how the vague and overbroad alleged inadequacies in the training caused their injuries. *See* Compl. ¶¶ 111-187. Without such allegations, Plaintiffs have failed to state a non-preempted cause of action. A contrary conclusion would "permit a jury to decide [Plaintiffs'] claims that the . . . training material the FDA required and approved through the PMA process were inadequate under state law." *Gomez v. St. Jude Med. Daig Div. Inc.*, 442 F.3d 919, 931 (5th Cir. 2006). For that reason, numerous courts have rejected virtually identical claims against Essure. *McLaughlin*, 172 F. Supp. 3d at 817-18; *De La Paz*, 159 F. Supp. 3d at 1096; *Norman*, 2016 WL 4007547, at *5; *Noris*, RJN, Ex. B. at 25:16-17. This Court should do the same.

D. Federal Law Preempts Plaintiffs' Failure To Warn Claims.

In their first, second, and fifth causes of action, Plaintiffs allege that Bayer "breached [its] duty in that [it] failed to warn Plaintiffs and their physicians by not reporting the risk of serious defects and life-altering complications." Compl. ¶ 191; *see also, e.g.*, *id.* ¶¶ 192, 228. These claims are preempted by federal law because they rest on the theory that Bayer had a duty to warn Plaintiffs and their treating physicians beyond the statements FDA required.

Federal courts have routinely held that state-law claims that would require warnings or information in addition to the FDA-mandated labeling are "precisely the type[s] of state requirement[s] that [are] 'different from or in addition to' the federal requirement[s] and therefore [are] preempted." *In re Medtronic*, 623 F.3d at 1205; *accord Gomez*, 442 F.3d at 929 ("[T]he PMA requirements preempted Texas state product-liability claims arising from a Class III medical device, including claims of defective design, failure to warn, and inadequate labeling, because those claims related to areas specifically covered in the PMA process and sought to impose requirements that were 'different from and, indeed, conflict with' the results of the PMA process."); *McMullen v. Medtronic, Inc.*, 421 F.3d 482, 488 (7th Cir. 2005); *Caplinger*, 784 F.3d at 1345; *Perez*, 711 F.3d at 1118; *Wolicki-Gables v. Arrow Int'l, Inc.*, 634 F.3d 1296, 1301-02 (11th Cir. 2011); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 236 (6th Cir. 2000); *Martin*, 2017 WL 825410, at *7. For this reason, numerous courts have held that a "plaintiff cannot bring [such] a claim [that] defendants failed to warn plaintiff personally . . . because such a claim would be expressly preempted as imposing obligations beyond those of the FDCA." *Norman*, 2016 WL 4007547, at *3-4; *see also Richardson*, 2016 WL 4546369, at *9; *Lance*, slip. op. at 15-16 (RJN, Ex. D).

Plaintiffs' allegations that Bayer could have unilaterally provided additional warnings through the "Changes Being Effected" process, *see, e.g.*, Compl. ¶¶ 44(e), 46, 50, 52(c), 78 (citing 21 C.F.R. § 814.39), does not save their claims. "Because § 814.39 *permits*, but does not *require*, a manufacturer to provide interim supplemental warnings pending approval by the FDA, a common-law duty to provide such a warning imposes an additional obligation" and is expressly preempted. *McMullen*, 421 F.3d at 489-90 (emphasis added); 21 C.F.R. § 814.39(d). In other words, "[w]here a federal requirement permits a course of conduct and the state makes it obligatory, the state's requirement is in addition to the federal requirement and thus is preempted." *In re Medtronic*, 623 F.3d at 1205; *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1234 (9th Cir. 2013) (Watford, J., concurring) (claim for failure to give post-sale warnings preempted because federal regulations permit but *do not require* manufacturers to issue such warnings).

E. Federal Law Preempts Plaintiffs' Failure To Report Claims.

Plaintiffs' failure to warn claims based on Bayer's alleged failure to report adverse events or other information to FDA are also preempted. These claims are impliedly preempted because Plaintiffs do not sufficiently allege a "causal link" between any failure to report adverse events and their alleged injuries. *See, e.g.*, *De La Paz*, 159 F. Supp. 3d at 1093, 1099; *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1235 (9th Cir. 2013) (Watford, J., concurring) ("Because [plaintiffs] predicate their claim on Medtronic's reporting duty to the FDA, as they must to avoid express preemption, the [plaintiffs] face a causation hurdle that would not otherwise exist. To prevail, they will ultimately have to prove that if Medtronic had properly reported the adverse events to the FDA as required under federal law, that information would have reached plaintiff's doctors in time to prevent his injuries.").

Plaintiffs claim in conclusory fashion that, had Bayer "timely and adequately reported the adverse events to the FDA, it would have effectively warned physicians, including Plaintiffs' physician[s]," Compl. ¶ 243, but they never explain how reporting adverse events *to FDA* would have warned *Plaintiffs and their physicians* or allege any facts to show such an outcome is plausible. *See Norman*, 2016 WL 4007547, at *4 ("[P]laintiff fails to plead facts that plausibly connect defendants' alleged reporting violations to her injuries."). Plaintiffs allege that Essure would have been considered "adulterated" and withdrawn from the market had Bayer reported adverse events, Compl. ¶ 82, but the adverse events that Plaintiffs claim Bayer had a duty to report were in FDA's possession before many—if not all—of the Plaintiffs had Essure placed in their fallopian tubes. *See id.* ¶¶ 65-67 (describing results of 2010-2011 inspection); *id.* ¶¶ 75-77 (describing results of 2012-2013 inspections).[3] Bayer's actions thus could not have impacted Plaintiffs' decisions whether to undergo the Essure procedure. The situation is thus similar to *De La Paz*, where this Court found that "De La Paz . . . failed to plausibly show that her injuries would have been prevented if Bayer

[3] Though Plaintiffs fault Bayer for failing to warn FDA of 30,000 complaints about Essure, *see, e.g.*, Compl. ¶¶ 83, 215 there is no obligation to blindly report all "complaints" to FDA. The regulations require "[e]ach *manufacturer* [to] review *and evaluate* all complaints to determine whether an investigation is necessary." 21 C.F.R. § 820.198(b) (emphasis added); *see also id.* § 820.198(d). There is no FDA finding that the alleged 30,000 complaints were reportable adverse events, and Plaintiffs concede that FDA reviewed the complaints during inspections in 2011 and 2013.

had properly reported the perforation events—a necessary element of her failure-to-warn-the-FDA claim"—because "FDA became aware of these adverse events more than a year before De La Paz underwent the procedure." 159 F. Supp. 3d at 1097. So too here.

Moreover, FDA has *never* withdrawn its approval of Essure. It has been aware for years of the adverse events that Plaintiffs claim Bayer failed to timely report, *see* Compl. ¶¶ 65-85, but after reviewing the same allegations made here, FDA found "no conclusive evidence in the literature indicating any new or more widespread complications definitely associated with Essure," RJN, Ex. N (FDA Activities) at 5, and reaffirmed that "Essure remains an appropriate option for the majority of women seeking a permanent form of birth control," RJN, Ex. F (News Release).

As *Norman* held, Plaintiffs' attempt to invoke FDA's recent boxed warning and Patient Decision Checklist only further undermines their claims and confirms why they are preempted. 2016 WL 4007547, at *4. After holding a public hearing, during which FDA considered the allegedly withheld events Plaintiffs raise here, *see* Compl. ¶ 106, FDA did not require Bayer to change its disclosures on the percentage of patients who may be injured, the number of adverse events, or the rate of unintended pregnancies. Instead, FDA proposed (and later adopted) a "boxed warning" for all "devices of this type." RJN, Ex. O (Final Guidance) at 5-6. This "new *type* of warning did not change any of the warnings' substance," *Norman*, 2016 WL 4007547, at *4. Rather, the same information was already in Essure's labeling:

Prior Essure Labeling	**Current Boxed Warning** *RJN, Ex. O (Final Guidance)*
• "To reduce **risk of uterine perforation**, terminate if excessive force is required to achieve cervical dilation . . . ." RJN, Ex. L (2013 IFU) at 2.	• "Some patients implanted with the Essure System for Permanent Birth Control have experienced and/or reported adverse events, including **perforation of the uterus and/or fallopian tubes**, identification of inserts in the **abdominal** or **pelvic device cavity, persistent pain**, and suspected **allergic or hypersensitivity reactions**. If the device needs to be
• "1.8% (12/682) of Essure clinical trial patients had device related **perforations**." RJN, Ex. L (2013 IFU) at 2; *see also* RJN, Ex. P (2008 IFU) at 2 ("A small percentage of women in the Essure procedure clinical trials (1.8% or 12/682 patients) were identified as having device related **tubal perforations**.")	

• "Potential adverse events" include "[p]erforation of **internal bodily structures other than the uterus and fallopian tube**." RJN, Ex. P (2008 IFU) at 2.	removed to address such adverse event, **a surgical procedure will be required.**" (Guidance at 9).
• "A very small percentage of women in the Essure procedure clinical trials reported recurrent or **persistent pelvic pain.**" RJN, Ex. P (2008 IFU) at 2.	
• "Patients who are **allergic to nickel** may have an **allergic reaction** to the inserts. **Symptoms** include rash, itching and hives." RJN, Ex. Q (2013 PIB) at 8; *see also* RJN, Ex. R (2008 PIB) at 4, 8.	
• "[I]f device removal is required for any reason, it will likely **require surgery**, including an **abdominal incisions** and general anesthesia, and possible hysterectomy." RJN, Ex. P (2008 IFU) at 2.	

Thus, Plaintiffs' conclusory assertion that if Bayer had "timely and adequately reported the adverse events to the FDA," Plaintiffs and their physicians would have been deterred from obtaining Essure, is insufficient to allege causation. Compl. ¶¶ 197, 243; *see De La Paz*, 159 F. Supp. 3d at 1097. As in *Norman* and *De La Paz*, this Court should dismiss the claim.

F. Federal Law Preempts Plaintiffs' Misrepresentation Claims.

In their first, third, fourth, and fifth causes of action, Plaintiffs allege that Bayer negligently and fraudulently misrepresented the safety and efficacy of Essure to Plaintiffs and their physicians. *See, e.g.*, Compl. ¶¶ 203 (Bayer "knowingly and negligently disseminated inaccurate and misleading information"); 257 (Bayer "breach[ed] [its] express warranties"); 270 (Bayer "breach[ed] [its] implied warranties"); 278 (Bayer "made affirmative representations . . . that Essure was safe and effective—while concealing the material facts"). As other courts, including this one, have held regarding highly similar allegations, *see*, *e.g.*, *De La Paz*, 159 F. Supp. 3d at 1097-99; *Norman*, 2016 WL 4007547, at *3-6; *Richardson*, 2016 WL 4546369, at *9; *McLaughlin*, 2017 WL 697047, at *11-15; *Burrell*, 2017 WL 1955333, at *7-8, these claims are preempted because FDA approved language substantively the same as the alleged misrepresentations:

Alleged Misrepresentation	Labeling Statement Approved by FDA
• "[O]nly FDA approved female sterilization procedure to have **zero pregnancies** in the **clinical trials**." Compl. ¶ 93(a).	• "In the Essure **clinical studies, zero (0) pregnancies were reported** in women who had the Essure Inserts for up to five years." RJN, Ex. Q at 12 (2013 PIB).
• Essure is "[s]**urgery-free**." Compl. ¶ 93(b). • "Essure® eliminates the risks, **discomfort**, and **recovery time** associated with **surgical procedures**." Compl. ¶¶ 93(c), 93(f). • Essure "requires **no down time** for recovery." Compl. ¶ 93(c).	• Essure "**[d]oes not require surgery**." *See* RJN, Ex. Q at 4 (2013 PIB). • The "Benefits of Essure," include that it is "**Non-Surgical**," that "**No General Anesthesia** [is] Required," and that "[m]ost women return to **normal activity** within one to two days." *See* RJN, Ex. Q at 5 (2013 PIB).
• Essure is **"[w]orry free."** Compl. ¶ 93(c).	• "Essure may be right for you if . . . You would like to **stop worrying** about getting pregnant." RJN, Ex. Q at 4 (2013 PIB).
• Essure is "a '**simple procedure** performed in your doctor's office.'" Compl. ¶ 93(c). • "[C]orrect placement . . . is **performed easily** because of the design of the microinsert." Compl. ¶ 93(h).	• Essure "may be right" for those who "prefer a method or procedure that . . . [i]s **simple** and does not take a lot of time." *See* RJN, Ex. Q at 4 (2013 PIB). • "Essure is a **simple procedure** that can be done in **10 minutes in your doctor's office**." *See* RJN, Ex. Q at 5 (2013 PIB).
• "[T]he Essure inserts . . . remain visible outside your tubes, so your **doctor can confirm** they're properly in place." Compl. ¶ 93(d).	• "Ideally, 3 to 8 expanded outer coils should be trailing into the uterus." *See* RJN, Ex. L at 8 (2013 IFU). • "After 3 months, a doctor will administer the Essure **Confirmation Test.** The test will **verify** that the inserts are in their **correct location**." RJN, Ex. Q at 6 (2013 PIB).
• "[T]he Essure® inserts **stay secure**, forming a **long protective barrier against pregnancy**." Compl. ¶ 93(d). • Essure "works with your body to create a **natural barrier** against pregnancy." Compl. ¶ 93(i).	• "The [Essure] insert expands upon release to conform to and acutely **anchor** in the tubal lumen[, which] elicits a benign tissue in-growth that permanently occludes the fallopian tube, resulting in contraception." RJN, Ex. L at 1 (2013 IFU). • "Over the next 3 months, your body will form . . . **a natural barrier** within the fallopian tubes." *See* RJN, Ex. Q at 6

Alleged Misrepresentation	Labeling Statement Approved by FDA
	(2013 PIB). • "Essure is a permanent birth control procedure that works with your body to create a **natural barrier** against pregnancy." RJN, Ex. Q at 4 (2013 PIB)
• "[T]he Essure® inserts are made from the same trusted, silicone free material used in **heart stents**." Compl. ¶ 93(e).	• "These same materials have been used for many years in **cardiac stents** and other medical devices placed in other parts of the body." *See* RJN, Ex. Q at 11 (2013 PIB).
• "Essure® is the **most effective** permanent birth control available – even more effective than tying your tubes or a vasectomy." Compl. ¶ 93(g).	• Comparing vasectomy, tubal ligation, and other methods of contraception, **each listing a higher rate of failure** than Essure. *See* RJN, Ex. Q at 15-19 (2013 PIB). • Essure is **"99.83% effective."** *See* RJN, Ex. Q at 5, 10, 12 (2013 PIB).
• "[P]hysicians must be **signed-off** to perform Essure® procedure." Compl. ¶ 97(a).[4]	• "Device to be used only by physicians who **are knowledgeable hysteroscopists**; have read and understood the Instructions for Use and Physician Training Manual; and have **successfully completed the Essure® training program**." RJN, Ex. L at 1 (2013 IFU).
• "[I]n order to be trained in Essure® you must be a **skilled operative hysteroscopist**." Compl. ¶ 97(c).	• The Essure device should "be used only by physicians who **are knowledgeable hysteroscopists.**" RJN, Ex. L at 1 (2013 IFU).
• "[T]he **PET fiber**s are what caused the **tissue growth**." Compl. ¶ 93(i).	• "**PET Fiber causes tissue in-growth** into and around the insert, facilitating insert retention and pregnancy prevention." *See* RJN, Ex. L at 1 (2013 IFU).

Because these purported "misrepresentations" and "warranties" track statements approved by FDA, Plaintiffs' claims for negligent and fraudulent misrepresentation and violation of consumer-

[4] Plaintiffs also allege Bayer represented that "qualified Essure® physicians" must perform a procedure "every 6-8 weeks," and that Bayer "signed off" on physicians who had not done so. Compl. ¶ 97(d). However, Plaintiffs do not allege that any of their physicians were among those who failed to meet this alleged standard.

protection laws are expressly preempted. *See* 21 U.S.C. § 360k(a). *De La Paz*, *Norman*, *McLaughlin*, and *Burrell* all dismissed claims of the same misrepresentations alleged here for this reason. *See De La Paz*, 159 F. Supp. 3d at 1098 (dismissing misrepresentation and warranty claims because "each of De La Paz's examples is a statement that has been approved, or even required, by the FDA as a descriptor for Essure."); *id.* (dismissing as preempted plaintiff's claims for "negligent misrepresentation [and] fraudulent misrepresentation" because "the statements conformed to statements approved by the FDA"); *Norman*, 2016 WL 4007547, at *5 (dismissing plaintiff's misrepresentation claims because alleged misstatements were "so similar to the approved language as to be substantively the same."); *McLaughlin*, 2017 WL 697047, at *11-15 (dismissing nearly all of plaintiffs' fraudulent misrepresentation claims as expressly preempted); *Burrell*, 2017 WL 1955333, at *7-8 (dismissing plaintiffs' misrepresentation and warranty claims as preempted); *see also Richardson*, 2016 WL 4546369, at *9 (dismissing plaintiffs' warranty and misrepresentation claims). This Court should do the same.

Furthermore, to the extent that Plaintiffs' claims turn on statements Bayer made at the September 2015 FDA hearing, *see* Compl. ¶ 106, they are immaterial to their claims because Plaintiffs' devices had already been placed by that time. Any statements made by Bayer after Plaintiffs had their devices placed in their bodies could not have induced them to have the devices placed at an earlier time.

II. PLAINTIFFS' CLAIMS FAIL TO SATISFY FEDERAL PLEADING STANDARDS.

Plaintiffs' complaint also fails for the separate reason that it does not state any valid cause of action. First, all of the claims fail to plead adequately that Bayer's actions caused Plaintiffs' alleged injuries, a necessary element of each claim. Second, Plaintiff's misrepresentation and fraud claims fail because they do not adequately establish that each Plaintiff and her physician relied on the supposed misrepresentations or plead fraud with sufficient particularity. Third, their implied-warranty claim fails because they do not allege privity.

A. Plaintiffs Fail To Plead Causation Adequately.

California law requires that Plaintiffs "allege facts . . . to explain how the conduct caused or

contributed to [their] injur[ies]." *Bockrath v. Aldrich Chem. Co.*, 21 Cal. 4th 71, 78 (1999). Causation is thus a basic element of each Plaintiff's causes of action, and they fail to plead that it exists for any of their claims. They should thus be dismissed.

Plaintiffs do not allege facts explaining how any alleged wrongful act by Bayer actually caused their injuries. For most of the claims, they states only legal boilerplate that, "[a]s a proximate and legal result" of Bayer's actions, "Plaintiffs suffered and will continue to suffer [injuries]." Compl. ¶ 216; *see also id.* ¶¶ 248, 290 (similar). These allegations of causation are nothing "more than labels and conclusions, and a formulaic recitation of th[is] element[] of a cause of action." *Twombly*, 550 U.S. at 570; *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009).

With no facts that support a causal link between alleged wrongdoing by Bayer and Plaintiffs' injuries, the Complaint simply does not provide "enough *facts* to state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570 (emphasis added); *see* p.8, *supra*. Because causation is a required element of each theory Plaintiffs raise, this Court cannot infer that the right to recovery is plausible. Plaintiffs' reliance on mere "labels and conclusions," *Twombly*, 550 U.S at 555, makes their Complaint precisely the sort of "unadorned, the-defendant-unlawfully-harmed-me accusation" that the Supreme Court has held insufficient, *Iqbal*, 556 U.S. at 678. The Complaint should be dismissed for this additional reason, as multiple courts have held in other Essure cases. *See, e.g.*, *McLaughlin*, 172 F. Supp. 3d at 817-18, 824, 836; *De La Paz*, 159 F. Supp. 3d at 1095; *Norman*, 2016 WL 4007547, at *6.

B. Plaintiffs' Fraud And Misrepresentation Claims Are Not Adequately Pled.

Plaintiffs allege that Bayer committed fraud by "intentionally, willfully, and maliciously conceal[ing] and/or suppress[ing]" material facts regarding Essure's safety and effectiveness from Plaintiffs and their physicians. Compl. ¶¶ 72, 279. They also claim that Bayer engaged in negligent misrepresentations. Compl. ¶¶ 203-04, 86-110. Rule 9(b) applies to both of these claims. *UMG Recordings, Inc. v. Global Eagle Entm't, Inc.*, 117 F. Supp. 3d 1092, 1106 (C.D. Cal. 2015) ("Claims for fraud and negligent misrepresentation must meet the heightened pleading requirements of Rule 9(b)."); *U.S. Concord, Inc. v. Harris Graphics Corp.*, 757 F. Supp. 1053, 1058 (N.D. Cal.

1991) (dismissing fraud and negligent misrepresentation claims for failing to satisfy Rule 9(b)'s particularity requirements).

Under this heightened pleading standard, Plaintiffs must "state the time, place, and specific content of the false representations as well as the identities of the parties to the misrepresentation." *Edwards v. Marin Park, Inc.*, 356 F.3d 1058, 1066 (9th Cir. 2004). In other words, they must allege "the who, what, when, where, and how" of the fraud. *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1106 (9th Cir. 2003). Like the complaint in *McLaughlin*, the Complaint here "makes no effort to inject[] precision by either pleading the date, place or time of the alleged fraud or by using any alternative means to substantiate the allegations." 172 F. Supp. 3d at 829. Beyond overbroad allegations as to "the mode of communication for each alleged misrepresentation," *id.*, Plaintiffs' Complaint does not specifically allege who was responsible for the supposedly fraudulent utterances, or when they were made. The Complaint also fails to indicate *when*, *where*, and *how* each Plaintiff encountered or relied upon any of the myriad misstatements alleged. These are necessary parts of their claims, and without them, Bayer is left without notice of the precise misconduct that Plaintiffs believe rose to the level of actual fraud. As *McLaughlin* recognized, this is precisely the sort of prejudice that Rule 9(b) is designed to avert. *See* 172 F. Supp. 3d at 829. Because Plaintiffs have not satisfied this burden, their fraud claims should be dismissed. *See, e.g.*, *Kearns*, 567 F.3d at 1126 (dismissing claims pursuant to Rule 9(b) because plaintiff failed to "specify when he was exposed to [defendant's representations] or which ones he found material"); *Herrington v. Johnson & Johnson Consumer Cos., Inc.*, No. 09-cv-1597, 2010 WL 3448531, at *7, *11 (N.D. Cal. Sept. 1, 2010) (dismissing fraud and negligent misrepresentation claims under Rule 9(b) where plaintiffs "do not plead the circumstances in which they were exposed to these statements," and "do not plead upon which [of these] representations they relied"); *In re Hydroxycut Mktg. & Sales Pracs. Litig.*, No. 09-md-2087, 2011 WL 3844217, *2-3 (S.D. Cal. Aug. 29, 2011) (dismissing same because "[a]lthough Plaintiff quotes the Hydroxycut website, product labels, inserts and other advertising in general . . . Plaintiff fails to specify that he was exposed to these statements, when he was exposed to them, and which material he relied upon in making his decision to purchase and ingest" them).

Plaintiffs' fraud and negligent misrepresentation claims should also be dismissed because Plaintiffs do not plead "*justifiable reliance*" on the alleged misstatements. *Kearns v. Ford Motor Co.*, 567 F.3d 1120, 1126 (9th Cir. 2009) (citing *Engalla v. Permanente Med. Grp., Inc.*, 15 Cal. 4th 951, 974 (1997)). Among other things, Plaintiffs fail to allege that they actually reviewed, saw, heard, or relied upon any specific alleged misrepresentations identified in the complaint. *See* Compl. ¶¶ 86-110, 118-187. In other words, they have "alleged insufficient facts to support an inference of causation" or reliance—a necessary element of their claims. *Norman*, 2016 WL 4007547, at *6. They should thus be dismissed.

C. Plaintiffs' Implied Warranty Claims Fail As A Matter of Law.

Plaintiffs' claim for breach of implied warranty claim also fails because they do not allege a key element of the cause of action: privity between themselves and Bayer. "Privity of contract is a prerequisite in California for recovery on a theory of breach of implied warranties of fitness and merchantability." *Blanco v. Baxter Healthcare Corp.*, 158 Cal. App. 4th 1039, 1058 (4th Dist. 2008); *see also Evraets v. Intermedics Intraocular, Inc.*, 29 Cal. App. 4th 779, 788 (2d Dist. 1994) ("It is settled law in California that privity between the parties is a necessary element to recovery on a breach of an implied warranty of fitness for the buyer's use. . . ."). Plaintiffs do not allege that privity of contract existed between themselves and Bayer. Plaintiffs received Essure not from Bayer but from their physicians. "There is no privity between the original seller and a subsequent purchaser who is in no way a party to the original sale." *Blanco*, 158 Cal. App. 4th at 1059.

III. THE COURT LACKS PERSONAL JURISDICTION OVER THE NON-CALIFORNIA PLAINTIFFS' CLAIMS AGAINST BAYER CORPORATION AND BAYER HEALTHCARE PHARMACEUTICALS INC.

Plaintiffs are seven unrelated women from five different states, who have misjoined their claims in a single complaint. *See* Fed. R. Civ. P. 20, 21. "[A] State may authorize its courts to exercise personal jurisdiction over an out-of-state defendant if the defendant has 'certain minimum contacts with [the State] such that the maintenance of the suit does not offend traditional notions of fair play and substantial justice.'" *Daimler AG v. Bauman*, 134 S. Ct. 746, 754 (2014). Sufficient

minimum contacts can be established in two ways: showing general jurisdiction or specific jurisdiction. *Id.* Neither standard is satisfied here.

Plaintiffs fail to show that Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. are "at home" in California, which would trigger general jurisdiction. *Daimler*, 134 S. Ct. at 760-61 & n.19. Neither Bayer Corporation nor Bayer HealthCare Pharmaceuticals Inc. is incorporated in or has its principal place of business in California.[5] *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 918-20 (2011). And Plaintiffs have not pleaded facts that demonstrate that this is an "exceptional" case in which Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. are nonetheless "at home" in California. *Daimler*, 134 S. Ct. at 760, 761 n. 19; *cf. BNSF Ry. v. Tyrrell*, 137 S. Ct. 1549, 1558 (2017) (giving *Perkins v. Benguet Consolidated Mining Co.*, 342 U.S. 437 (1952), where a corporation relocated all of its operations from the Philippines to Ohio during war, as an example of an "exceptional case").

Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. also are not subject to specific personal jurisdiction in California with respect to the claims of five of the seven Plaintiffs who are not California citizens.[6] *Bristol-Myers Squibb Co. v. Superior Court of California, San Francisco Cty.*, No. 16-466, 137 S. Ct. 1773, 1780-82 (2017). The non-California Plaintiffs' claims against Bayer Corporation and Bayer HealthCare Pharmaceuticals Inc. lack the required "'relationship among the defendant, the forum, and the litigation.'" *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 (1984). The non-California Plaintiffs do not allege that they purchased their Essure devices in California, saw or relied on any alleged misrepresentations while in California, had their devices placed or removed in California, received medical treatment from their physicians in California, or that their injuries have any other connection to California. Further, they do not allege that Bayer Corporation or Bayer HealthCare Pharmaceuticals Inc. owns or has owned an Essure manufacturing facility in California. Thus, the non-California Plaintiffs fail

[5] Bayer Corporation is an Indiana Corporation with its principal place of business in New Jersey; Bayer HealthCare Pharmaceuticals Inc. is a Delaware corporation with its principal place of business in New Jersey.

[6] Only Plaintiffs Gordon and Peters allege that they are citizens of California. *See* Compl. ¶¶ 12, 15.

to meet their burden to demonstrate that specific jurisdiction exists. *See Bristol-Myers*, 137 S. Ct. at 1781-82.

CONCLUSION

For these reasons, Plaintiffs' claims should be dismissed.

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